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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,861	02/24/2004	Thomas P. Hedman	89188.0058	3669
<div>26021 7590 09/18/2007 HOGAN &amp; HARTSON L.L.P. 1999 AVENUE OF THE STARS SUITE 1400 LOS ANGELES, CA 90067</div>				
			EXAMINER OLSON, ERIC	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 09/18/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/786,861	Applicant(s) HEDMAN, THOMAS P.	
	Examiner Eric S. Olson	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>February 1, 2005</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

This application is a continuation in part of US application 10/230671, filed August 29, 2002, currently pending, and claims benefit of provisional applications 60/498790, filed August 28, 2003, and 60/316287, filed August 31, 2001. Claims 1-30 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted August 23, 2004 is acknowledged wherein the specification is amended to indicate continuity.

### ***Claim Objections***

Claims 1-9 and 19-21 are objected to because of the following informalities: they are drawn to methods of treating "invertebrate discs." Invertebrates have no spinal cord and no spinal discs. They do not suffer from scoliosis. Based on the specification, it is suggested that Applicant intended to claim a method of stabilizing intervertebral discs. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 15, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al. (US patent 5607965, cited in PTO-892) Kondo et al.

discloses a proanthocyanidin useful for lowering cholesterol.(column 2, lines 53-59) An example is given of an injectable proanthocyanidin solution in physiological saline. (column 8, lines 1-14) This composition comprises the same elements as the device recited in instant claims 10, 11, 15, and 22-24. Therefore it inherently possesses the same utility and physiological properties, anticipating the claimed invention. Note that the intended use of a composition does not render the composition patentable over the prior art if the prior art composition is capable of use for the same purpose.

Claims 10, 11, 15, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang. (US patent 5929038, cited in PTO-892) Chang discloses iridinoid compounds useful for inhibiting hepatitis B DNA replication. (column 1, lines 22-27) Genepin is disclosed as a specific embodiment. (column 2, lines 14-17) An example is provided of an injectable composition comprising an iridinoid compound in physiological saline. (column 11, lines 15-27) This composition comprises the same elements as the device recited in instant claims 10, 11, 15, and 22-24. Therefore it inherently possesses the same utility and physiological properties, anticipating the claimed invention. Note that the intended use of a composition does not render the composition patentable over the prior art if the prior art composition is capable of use for the same purpose.

Claims 10, 11, 13, 15, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Murad. (US patent 5804168, cited in PTO-892) Murad discloses a composition for treating damaged or inflammatory skin, comprising various ingredients

including a proanthocyanidin. (column 3, lines 29-64) These compositions can be administered by the topical or transdermal routes, among others. (column 9, lines 20-25) They can be formulated as controlled release dosage forms as well. (column 6, lines 6-12) This composition comprises the same elements as the device recited in instant claims 10, 11, 15, and 22-24. Therefore it inherently possesses the same utility and physiological properties, anticipating the claimed invention. Note that the intended use of a composition does not render the composition patentable over the prior art if the prior art composition is capable of use for the same purpose.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 14, 17, 18, 25, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kondo et al. (US patent 5607965, cited in PTO-892) The disclosure of Kondo et al. is discussed above. Kondo et al. does not disclose a sterile syringe and needle containing a proanthocyanidin composition.

It would have been obvious to one of ordinary skill in the art at the time of the invention to dispense the injectable composition taught by Kondo et al. in a syringe and needle. One of ordinary skill in the art would have been motivated to modify the invention in this manner because Kondo et al. discloses that the solution is intended for

injection. Injecting a solution in physiological saline using a syringe and needle is a routine and predictable procedure for one of ordinary skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 12, 14, 17, 18, 25, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang. (US patent 5929038, cited in PTO-892) The disclosure of Chang is discussed above. Kondo et al. does not disclose a sterile syringe and needle containing a proanthocyanidin composition.

It would have been obvious to one of ordinary skill in the art at the time of the invention to dispense the injectable composition taught by Chang in a syringe and needle. One of ordinary skill in the art would have been motivated to modify the invention in this manner because Chang discloses that the solution is intended for injection. Injecting a solution in physiological saline using a syringe and needle is a routine and predictable procedure for one of ordinary skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 16-18, and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US patent 5804168, cited in PTO-892) as applied to claims 10, 11, 13, 15, and 22-24 above, and further in view of Ng et al. (US patent 5336505, cited in PTO-892) The disclosure of Murad is discussed above. Murad does not disclose a time-release delivery system that is an ointment.

Ng et al. discloses polymers that can be used to construct controlled release dosage forms such as ointments for controlled topical delivery. (column 2, lines 20-56, column 5, lines 19-28)

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate the compositions of Murad in the controlled release topical ointment of Ng et al. One of ordinary skill in the art would have been motivated to use this formulation because Murad already discloses a composition suitable for topical use and suggests that it be formulated in a controlled release formulation. Applying the ointment formulation of Ng et al. to any specific active agent is a routine and predictable activity for one of ordinary skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-10, 14-16, 18-21, 25-27, and 29-35 of copending Application No. 11/346464. (Unpublished, cited in PTO-892, herein referred to as '464) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3, 5-10, 14-16, 18-21, 25-27, and 29-35 of '464 anticipate the claimed invention. Claim 1 of '464 claims a method comprising contacting the collagenous tissue within an intervertebral disc with a crosslinking agent. Claim 3 indicates that the spine treated has a pre-existing deformity, including scoliosis. Claims 5-10 and 14 introduce the same additional limitations found in instant claims 2-10. Claims 15, 16, 18-21, 25-27, and 29-35 of '464 are drawn to a device having the same composition and physical form (e.g. a syringe, time-release capsule, etc.) as instant claims 14-30. Therefore the claimed invention is anticipated by '464.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

No claims are allowed in this application.

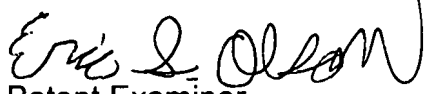


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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